REMARKS/ARGUMENTS

This Amendment and the accompanying Request for Continuing Examination is filed in response to the second and Final Official Action dated March 23, 2006. In that claims 1-5, 7 and 9-14 are now believed to be in condition for allowance for the reasons presented below, a Notice of Allowance is respectfully requested.

Claims 1-5, 7, 9-12 and 14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 4,860,750 to Frey et al. in view of U.S. Patent 6,080,188 to Rowley et al. These rejections are respectfully traversed.

The appropriate approach for assessing non-obviousness was set out by the U.S. Supreme Court in *Graham v. John Deere*, 383 U.S. 1 (1966):

> Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolve. Against this background, the obviousness or non-obviousness of the subject matter is determined. Such secondary considerations as commercial success, long-felt but non-unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

For the purposes of the present analysis, the "scope and content of the prior art" includes the Frey et al. U.S. Patent 4,860,750, the Rowley et al. U.S. Patent 6,080,188 and the Bradshaw U.S. Patent 5,486,202.

The Frey et al. '750 patent, like the present invention, describes an implantable medical device that comprises an implantable pulse generator contained within a hermetically sealed housing along with a device connector affixed to the housing where the device connector has first and second side surfaces and a front surface and having at least one longitudinally extending bore formed inwardly from a front surface adapted to receive a proximal terminal of a medical lead therein, the proximal terminal including a conductive pin at a proximal end of the terminal. An electrical contact is disposed within the device connector and is positioned to cooperate with the conductive pin on the proximal end of the lead when the proximal terminal is fully inserted into the longitudinal

bore of the device connector. Formed in the opposed side walls of the device connector is a channel 30 into which is adapted to slide a wedge member 35 that carries an upwardly extending convex/concave lead engaging member 31. The wedge member 35 is held in place within the device connector by inserting a pin 38 between bifurcated legs 40a and 40b which causes those legs to spread apart such that detent bumps 41a and 41b lock into notches 42a and 42b located in the channel 30, all is best seen in Figure 4a of the '750 patent.

The Rowley et al. '188 patent also describes a device connector-to-lead terminal connector for an implantable medical device where the implantable medical device has an implantable pulse generator contained within a hermetically sealed housing 13 and carries a device connector 15 that is affixed to a predetermined surface of the housing and where the device connector has a single side port extending inward from one side surface of the device connector. Further, the device connector includes a longitudinally extending bore formed inwardly from a front surface and that is adapted to receive a proximal terminal of a medical lead therein where the proximal terminal includes a conductive pin at a proximal end of the terminal. As shown in Figure 6 of the '188 patent, electrical contacts 68 and 69 are disposed in the device connector 61 and are positioned to cooperate with the conductive pin 71 when the proximal terminal 71 of the lead is fully inserted into the longitudinal bore.

Adapted to fit into the single side port is a handle actuated rotatable axle, one embodiment of which is shown in Figure 11 of the '188 patent. Surrounding the rotatable axle proximate its midpoint is a latex band 115. Rotation of the handle when the axle is inserted through the single side port provides a camming action on an insulated portion of the lead terminal to lock the lead terminal within the longitudinal bore 21.

The Bradshaw '202 patent describes an altogether different mechanism for locking a proximal terminal of a medical lead within a longitudinal bore 16 of a device connector of an implantable pulse generator. Its only relevance to the present invention appears to be that it incorporates an elastomeric washer 30 as a seal between a screw-on cap 24 and a surface of the device connector 20.

Having discussed the "scope and content of the prior art", attention is next directed to the second prong of the *Graham v. John Deere* considerations, the

"differences between the prior art and the claims at issue". Set forth below is a claim chart setting forth amended claim 1 and reflecting the differences between the subject matter sought to be patented and the prior art Frey '750, Rowley '188 and Bradshaw '202 references.

Claim Limitation	**Frey et al '750**	**Rowley et al. '188**	**Bradshaw et al '202**
(a) an implantable pulse generator contained within a hermetically sealed housing;	Yes.	Yes.	Yes.
(b) a device connector affixed to a predetermined surface of said housing, the device connector having first and second side surfaces and a front surface and having at least one longitudinally extending bore formed inwardly from the front surface adapted to receive a proximal terminal of a medical lead therein, the proximal terminal including a conductive pin at a proximal end of the terminal;	Yes.	Yes.	Yes.
(c) an electrical contact disposed in the device connector and positioned to cooperate with the conductive pin when the proximal terminal of the medical lead is fully inserted into the longitudinal bore;	Yes. 25 mates with 18.	Yes. Col. 4, lines 25-31.	Yes. Contact 22.
(d) said device connector having first and second side ports extending inwardly from said first and second side surfaces to intersect with the longitudinal bore in alignment with the contact;	No. Side ports 30 are not aligned with contact 18.	No. See col. 5, lines 13-18.	No. There are no side ports.
(e) an elastomeric tube inserted through one of the first and second side ports and oriented crosswise to the longitudinally extending bore, the elastomeric tube having a central lumen and a radial flange on opposed ends of said tube;	No. There is no elastomeric tube.	No – 118 does not have flanges on opposed ends.	No – Elastomeric washer 30 is not a flange on opposed ends of an elastomeric tube.

(f) a first latch member adapted to be insertable through the first side port, the first latch member including a pair of bifurcated legs extending into said lumen; and	No. Member 35 does not have its legs 40a and 40b inserted into the lumen of an elastomeric tube.	No. If the handle 110 is considered to be the first latch member, it does not have a pair of bifurcated legs extending into a lumen of an elastomeric tube that has radial flanges on opposed ends.	No. There is no latch member in a side post with bifurcated legs and no elastomeric tube whose lumen contains bifurcated legs.
(g) a second latch member insertable through the second side port into said lumen and having a tapered wedge surface adapted to spread the bifurcated legs of the first latch member apart and press the elastomeric tube against the conductive pin with a force sufficient to hold the conductive pin in place against the electrical contact when the first and second latch members are squeezed together, the radial flanges forming moisture impervious seals between the first and second side surfaces of the device connector and the first and second latch members.	No. Member 38 does not extend into a lumen of an elastomeric tube. It does not act to press an elastomeric tube against the pin 25 to hold pin 25 against contact 18 and there are no radial flanges on an elastomeric tube that create a moisture impervious seal between the sides of 15 and members 35 and 38.	No. There is not second latch member or a second side port and no seal between handle 111 and a side surface 15.	No. There are no latch members, no side ports, no elastomeric tube with a lumen and radial sealing flanges on opposed end.

Independent claim 7 is of a scope commensurate with the scope of claim 1 but is written in the Jepson style format. Thus, in focusing on the differences between the subject matter sought to be patented and the prior art, the differences highlighted in the above chart for elements (d), (e), (f) and (g) of claim 1 are applicable to elements (a), (b), (c) and (d) of claim 7.

Concerning the "level or ordinary skill in the art", applicants' attorney would submit that it is relatively high. This opinion is based on the known educational level of the inventors, the sophistication of the technology and the educational level of workers active in the implantable medical device field.

Given the differences between what applicant is claiming in independent claims 1 and 7 and the prior art as reflected in the above chart, it is submitted that the subject matter, as a whole, would not have been obvious at the time it was made to persons of

ordinary skill in the art and, accordingly, that the claimed invention is neither anticipated nor obvious in view of the prior art of record.

Applicants were the first to arrive at a solution of the problem of tightly engaging an electrical pin terminal on a medical lead with an electrical contact contained within the device connector and that simultaneously sealed the device connector against ingress of body fluids that might otherwise compromise the electrical integrity of the lead-to-contact connection and did not require the use of a locking setscrew.

As is pointed out at page 2 of applicants' specification, the use of a setscrew in combination with the electrical contact to engage the conductive pin on the lead with the contact necessarily results in an implantable medical device of a thickness greater than it need be. While the prior art Frey et al. '750 patent is also critical of the setscrew approach, it did not address the electrical integrity issue in that the wedges 35 and 43 do not hold the lead pin 25 against the contact block 18 nor does it provide a seal precluding body fluids from seeping down the channel 30 and the lead bore 53(a) or 53(b). Instead, the wedges 35 and 38 only cooperated with the silicon rubber strain relief reinforcement 26 on the lead 24 to inhibit pull-out of the lead from the longitudinally extending bore of the device connector 27.

The Office Action cites the Rowley et al. patent contending that it teaches providing an elastomeric tube (element 118 in Figure 11) for applying a tool-less frictional fixation means to a medical lead to avoid rough contact with the lead body while still providing the contact force necessary to fix the lead in place. Based on this, it is contended that it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an elastomeric tube in the Frey et al. device. It must be appreciated that applicants' tube is not used for protecting the silicon rubber of the lead's strain relief reinforcement but, instead, acts to firmly press the conductive pin on the pacing lead against the internal bore of the contact member 78. Thus, there is no motivation in the Rowley et al. patent or in the Frey et al. patent for combining the two references in the manner advanced in the Office Action.

Furthermore, there is nothing in this combination of references that would teach or suggest providing annular flanges on opposed ends of an elastomeric tube that is inserted through one of the side ports and whose lumen is used to contain the bifurcated

legs of a first latch member and a second latch that is used to spread the bifurcated legs to provide the necessary biasing force against the pin contact of the lead while at the same time creating a moisture impervious seal between the latch members and the side surfaces of the device connector.

It is submitted that applicants have come up with a significant advance in the art that is worthy of the grant of a patent thereon.

As the U.S. Supreme Court held in *Webster Lum. Co. v. Higgins*, 105 U.S. 580 (1881):

> "It is plain from the evidence, and from the very fact that it was not sooner adopted and used, that is did not, for years, occur ... to even the most skillful persons. It may have been under their very eyes, they may almost be said to have stumbled over it; but they certainly failed to see it, to estimate its value and bring it into notice ... Now that it has succeeded, it may seem very plain to anyone, that he could have done it as well. This is often the case with inventions of the greatest merit. It may be laid down as a general rule, though perhaps not an invariable one that if a new combination and arrangement of known elements produce a new and beneficial result, never attained before, it is evidence of invention."

CONCLUSION

By way of summary, then, in arguing for patentability, applicants have followed the methodology set out in *Graham v. John Deere* and after considering the scope and content of the prior art relied on in the rejection based on 35 U.S.C. §103(a) has provided an indication of the differences between the subject matter which applicants seek to patent and the prior art and given the non-obviousness of those differences, it is submitted that independent claims 1 and 7 are patentable over the prior art with the allowance of independent claims 1 and 7, dependent claims 2-5 and 9-14 should also be allowed.

A Notice to that effect is most respectfully solicited.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment filed in response to the Official Action of March 23, 2006, along with a Request for Continuing Examination in application Serial No. 10/748,426, filed on December 30, 2003, of David J. Hansen, et al. entitled "Device-to-Lead Terminal Connector for Implantable Tissue Stimulators" is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, postage prepaid, on April 26, 2006.

Date of Signature: April 26, 2006.

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On Behalf of Thomas J. Nikolai
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